

DOCKET NO. 11209.03

FEB 25 2005

In re: Application of:

For:

Serial No.:

Filed:

Olsen et al

EXTRACORPOREAL BLOOD CIRCUIT AIR REMOVAL SYSTEM AND METHOD

10/743,598

12-22-2003

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**INFORMATION DISCLOSURE STATEMENT TRANSMITTAL**

**CERTIFICATE OF MAILING UNDER 37 CFR 1.8:** I hereby certify that this **INFORMATION DISCLOSURE STATEMENT** and the paper(s), as described herein, are being deposited in the U.S. Postal Service, as first class mail, addressed to the Commissioner of Patents and Trademarks, P.O. Box 1450, Alexandria, VA 22313-1450 on this 23rd day of February, 2005.

Signature

Jo L. Brecht

Printed Name

Commissioner of Patents and Trademarks  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

We are transmitting herewith the attached:

- ☒ Information Disclosure Statement Transmittal
- ☒ Supplemental Information Disclosure Statement
- ☒ PTO FORM 1449
- ☒ Copies of cited Foreign Patents and Other Documents
- ☒ Return Postcard

**FEE CALCULATION**

- ☐ \$ 00.00 Pursuant to 37 CFR §1.97(b)
- ☐ \$ 00.00 Pursuant to 37 CFR §1.97(c) with Certification
- ☐ \$ 00.00 Pursuant to 37 CFR §1.97(e) with Certification
- ☐ \$240.00 Pursuant to 37 CFR §1.97(c) without Certification
- ☐ \$130.00 Pursuant to 37 CFR §1.97(d) with Certification

- ☐ Applicant hereby petitions for a \_\_\_\_\_ months' extension of time. If an additional extension of time is required, please consider this petition therefor.
- ☐ Applicant believes that no extension of time is required. However, if an extension of time is required, please consider this a petition therefor to provide for the possibility that applicant has inadvertently overlooked the need for an extension of time.
- ☒ Please charge any additional fees or credits to Deposit Account No. 13-2546 which may have been overlooked on this ~~Amendment~~ Transmittal with regard to this filing. A duplicate of this transmittal is enclosed.

Date

February 23, 2005

Jeffrey J. Hohenshell

Reg. No. 34,109

Telephone: (763) 391-9661



PATENT  
Docket: P-11209.03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant(s):	Robert W. Olsen, et al	)	Art Unit: 3761
		)	
Serial No.:	10/743,598	)	Examiner:
		)	
Filed:	12-22-2003	)	
For:	EXTRACORPOREAL BLOOD CIRCUIT AIR REMOVAL SYSTEM AND METHOD		

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

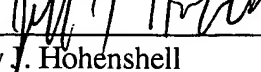
Dear Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application.

Consideration of each of the documents listed on the attached Form 1449 is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicant further requests that a copy of the Form 1449, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Respectfully submitted,

Robert W. Olsen, et al  
By their Representatives,

By:   
Jeffrey J. Hohenshell  
Attorney for Applicant  
Registration No. 34,109  
Telephone: (763) 391-9661  
Customer No.: 27581

**INFORMATION  
DISCLOSURE  
STATEMENT**

Atty. Docket No.: P-11209.03

Serial No.: 10/743,598

Applicant(s): Olsen et al

Filing Date: 12-22-2003

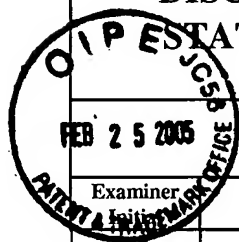
Group:

**U.S. PATENT DOCUMENTS**

Examiner	Document Number	Date	Name	Class	SubClass	Filing Date If Appropriate
	2002/0114731	08-22-2002	Stringer			
	2002/151804	10-17-2002	Gelfand et al			
	2003/135152	07-17-2003	Kollar			
	2004/084358	06-05-2004	O'Mahony			
	6,716,189	06-04-2004	Jarvik			
	6,730,267	05-04-2004	Stringer			
	6,689,315	02-10-2004	Linker			
	6,503,450	01-07-2003	Afzal			
	6,524,267	02-25-2003	Gremel et al			
	6,454,999	09-24-2002	Farhangnia			
	6,428,747	08-06-2002	Lemken			
	6,337,049	01-08-2002	Tamari			
	6,224,829	05-01-2001	Piplani			
	6,210,365	04-03-2001	Afzal			
	6,200,276	03-13-2001	Biesel et al			
	6,083,198	07-04-2000	Afzal			
	5,965,089	10-12-1999	Hammerquist et al			
	5,931,646	08-03-1999	Nogawa et al			
	5,876,611	03-1999	Shettigar			
	5,162,102	11-10-1992	Nogawa, et al			
	5,074,839	12-24-1991	Choksi et al.			
	5,055,198	10-08-1991	Shettigar			
	4,997,464	03-05-1991	Kopf			
	4,923,438	05-08-1990	Vasconcellos et al.			
	4,758,337	07-19-1988	Köhn et al.			
	4,572,724	02-1986	Rosenberg et al			
	4,411,783	10-1983	Dickens et al			
	3,507,395	04-1970	Bentley			

**EXAMINER****Date Considered**

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



<b>INFORMATION DISCLOSURE STATEMENT</b>			<b>Atty. Docket No.: P-11209.03</b>			<b>Serial No.: 10/743,598</b>		
			<b>Applicant(s): Olsen et al</b>					
			<b>Filing Date: 12-22-2003</b>			<b>Group:</b>		
<b>FOREIGN PATENT DOCUMENTS</b>								
		<b>Document Number</b>	<b>Date</b>	<b>Country</b>	<b>Class</b>	<b>SubClass</b>	<b>Translation</b>	
							<b>Yes</b>	<b>No</b>
		WO 02/064013	08-22-2002	WO				
		WO 02/26288	04-04-2002	WO				
		EP 1036567A2	02-09-2001	EP				
		DE 4326886A1	02-16-1995	DE				
		WO 96/24397	08-15-1996	WO				
		EP 0351980B1	04-06-1994	EP				
		WO 00/12155	03-09-2000	WO				
<b>OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)</b>								
		<i>Journal of Extra-Corporeal Technology</i> : "Rapid Pediatric Cardiopulmonary Support System," J.W. OJITO, ET AL., 1997; 29(2):96-99.						
		<i>Pediatric Cardiac Anesthesia</i> : "Extracorporeal Circulation and Circulatory Assist Devices in the Pediatric Patient," FRANK H. KERN, et al., 1997; 3rd Ed.:219-258.						
		<i>Journal of Extra-Corporeal Technology</i> : "Experimental Use Of An Ultra-Low Prime Neonatal Cardiopulmonary Bypass Circuit Utilizing Vacuum-Assisted Venous Drainage," EDWARD DARLING, et al., 1998; 30(4):184-89.						
		<i>Perfusion</i> : "Minimizing The Bypass Circuit: A Rational Step In The Development Of Paediatric Perfusion," MARTIN ELLIOTT, 1993; 8:81-86.						
		<i>Zasshi Journal</i> (English Abstract): "The Indications and Limitations of Open Heart Surgery Without Homologous Blood Transfusion in Children and Infants," MASANOBU MAEDA, et al., 1994; 42:1-7.						
		<i>Journal of Cardiovascular Surgery</i> : "Clear Prime for Infant Cardiopulmonary Bypass: A Miniaturized Circuit," ERIC WABEKE, et al., 1988; 29(2):117-22.						
		<i>Journal of Extra-Corporeal Technology</i> : "A Modification Of The Sarns Conducer Heat Exchanger As A Low Prime Pediatric Cardioplegia System," RONALD GORNEY, et al., 1994; 26(1):37-39.						
		<i>International Anesthesiology Clinics</i> : "Pediatric Cardiopulmonary Bypass: A Review of Current Practice," ROBERT C. GROOM, et al., 1996; 34:141-63.						
		<i>Journal of Extra-Corporeal Technology</i> : "Micro-Prime Circuit Facilitating Minimal Blood Use During Infant Perfusion," CHARLES M. TYNDAL JR., et al., 1987; 19(3):352-57.						
		<i>Ann. Thoracic Surgery</i> : "A Venous Reservoir For Cardiopulmonary Bypass In Newborns And Small Infants," JOHN L. OCHSNER, et al., 1988; 45:686.						
		<i>Proc. Eur. Society Artificial Internal Organs</i> : "Automation of Cardiopulmonary Bypass for Open Heart Surgery," P.H. MOOK, et al., 1978; 5:234-37.						
<b>EXAMINER</b>				<b>Date Considered</b>				

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<b>OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)</b>								
			<i>Perfusion</i> : "Mini-Circuit Cardiopulmonary Bypass With Vacuum Assisted Venous Drainage: Feasibility Of An Asanguineous Prime In the Neonate," CHRISTINE L. LAU, et al., 1999; 14:389-96.					
			<i>Artificial Organs</i> : "A Novel Technique for Cardiopulmonary Bypass Using Vacuum System for Venous Drainage with Pressure Relief Valve: An Experimental Study," SATOSHI TAKETANI, et al., 1998; 22(4):337-41.					
			<i>Perfusion</i> : "Paediatric Perfusion Practice in North America: An Update," ROBERT C. GROOM, ET AL., 1995; 10:393-401.					
			<i>Perfusion</i> : "Single Pump Mechanically Aspirated Venous Drainage (SPMAVD) for Cardiac Reoperation," 1996; 11:351-353 (Applicants only have page 351).					
			<i>Ann. Thoracic Surg</i> : "Minimally Invasive Coronary Artery Bypass Grafting," TEA E. ACUFF, M.D., et al., 1996; 61:135-7 (Applicants only have page 135).					
			<i>Ann. Thoracic Surg</i> : "Transpericardial Inferior Vena Caval Cannulation in Thoracic Aorta Operations," EUGENIO NERI, M.D., et al., 1996; 62:1208-1209 (Applicants only have page 1208).					
			<i>Ann. Thoracic Surg</i> : "Minimally Invasive Valve Operations," DELOS M. COSGROVE III, M.D., et al., 1998; 65:1535-9 (Applicants only have page 1535).					
			<i>Ann. Thoracic Surg</i> : "Augmented Femoral Venous Return," LYNN SOLOMON, M.D., et al., 1993; 55:1262-3 (Applicants only have page 1262).					
			Drawing provided by Miami Children's Hospital, drawn on July 7, 1997.					
			Specification Sheets of a venous assisted CB circuit, specification sheets sent between Miami Children's Hospital and Medtronic, Inc., earliest date is December 16, 1998 (7 pages).					
			Specification Sheets of a hybrid CB circuit, specification sheets sent between Miami Children's Hospital and Medtronic, Inc., earliest date is June 20, 1997.					
			Email relating to augmented venous return sent to PerfList@aol.com, PerfList@aol.com is a multiple recipient medical informational email group, sent on April 27, 1997.					
			Email relating to augmented venous return and minimally invasive procedures sent to PerfList@aol.com, PerfList@aol.com is a multiple recipient medical informational email group, sent on April 27, 1997.					
			Email relating to venous drainage sent from Brian Crawford CCP to Jorge Ojito on April 28, 1997.					
			Email relating to augmented venous return sent by Jorge Ojito on April 26, 1997.					
			<i>Ann. Thoracic Surgery</i> : "Assisted Venous Drainage Cardiopulmonary Bypass in Congenital Heart Surgery," JORGE OJITO, et al., 2001; 71:1267-72.					
<b>EXAMINER</b>				<b>Date Considered</b>				

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<b>OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)</b>			
		Ann. Thoracic Surgery: "Rapid Cardiopulmonary Support for Children with Complex Congenital Heart Disease," JEFFREY P. JACOBS, et al., 2000;70:742-50.	
		"Minimally Invasive & Bypass" computer search results, 1998.	
		"Minimally Invasive & Valve" computer search results, 1998.	
		"Intersept® Custom Tubing Pack with Carmeda® BioActive Surface" product label, 2003.	
		Facsimile transmission sheet from Elly Wierenga, Medtronic, Inc., regarding Carmeda® Data Analysis, September 14, 1998.	
		"Venous Pull Circuit" diagram.	
		<i>Journal of Thoracic and Cardiovascular Surgery</i> Copyright and Conflict of Interest Statement regarding manuscript entitled "Assisted Venous Drainage Cardiopulmonary Bypass: (AVDCPB) An Alternative Technique in Minimally Invasive Congenital Surgery" signature page, signed by Jorge Ojito, November 25, 1998.	
		May 4, 1999 correspondence from John A. Waldhausen, M.D., <i>The Journal of Thoracic and Cardiovascular Surgery</i> , to Redmond Burke, M.D. regarding his manuscript entitled "Assisted Venous Drainage Cardiopulmonary Bypass: an Alternative Technique in Minimally Invasive Congenital Cardiac Surgery."	
		June 28, 2000 correspondence from L. Henry Edmunds, Jr., M.D., Editor, <i>The Annals of Thoracic Surgery</i> , to Redmond P. Burke, M.D. regarding his paper entitled "Assisted Venous Drainage Cardiopulmonary Bypass: Safety and Efficacy in Congenital Heart Surgery."	
		Program and certificate of participation of Jorge Ojito at Sociedad Chilena de Circulacion Extracorporea, Vina del Mar, Chile, November 12-15, 1998.	
		"Assisted Venous Drainage Cardiopulmonary Bypass: Safety and Efficacy in Congenital Heart Surgery" presentation, JORGE OJITO.	
		Certificates of participation by Jorge Ojito Jornados Sobre Perfusion Pediatrica y Asistencia Circulatoria Mecanica, Buenos Aires, Argentina, November 17, 1998.	
		Cardiologia program, Caracas, Venezuela, June 6-10, 2000.	
		"Assisted Venous Drainage Cardiopulmonary Bypass: Safety and Efficacy in Congenital Heart Surgery," presented by JORGE OJITO, Mechanisms of Perfusion XVI, Lake Buena Vista, Florida, May 17-20, 2001.	
		"Assisted Venous Drainage During CPB: Safety and Efficacy in Congenital Heart Surgery," presented by JORGE OJITO, The 38 <sup>th</sup> Annual Scientific Meeting of Japanese Society of Pediatric Cardiology and Cardiac Surgery, 2002.	
		Comparison of claims in United States Patent No. 6,302,860 (Gremel, et al.) and United States Patent No. 6,337,049 (Tamari).	
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